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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/146,783	09/03/98	DEACON	N 9606Z-IY

HM12/0228

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EXAMINER	
PARKIN,J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/28/00

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/146,783	Deacon et al.
Examiner	**Group Art Unit**
Jeffrey S. Parkin, Ph.D.	1641

☒ Responsive to communication(s) filed on *3 Sep 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-119* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-119* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Restriction Requirement

Fax Response Pilot for Written Restriction Requirements

1. In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is (703) 305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. **Please limit the use of this dedicated Fax number to responses to Written Restrictions.**

Restriction/Election

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claims 1-29, drawn to a **non-pathogenic HIV-1 strain**, classified in class 435, subclass 236.

b. Group II, claims 30-48 and 85, drawn to a **method of inhibiting HIV-1 infection** by administering a therapeutic composition comprising a non-pathogenic HIV-1 isolate, classified in class 424, subclass 208.1.

c. Group III, claims 49-67 and 85, drawn to a **method of vaccinating subjects** with a therapeutic composition comprising a non-pathogenic HIV-1 isolate, classified in class 424, subclass 208.1.

d. Group IV, claims 68-79, drawn to a **method for the preparation** of non-pathogenic HIV-1 isolates from biological samples, classified in class 435, subclass 237.

e. Group V, claims 80-82, drawn to a **screening method** for the identification of putative antiviral compounds employing a *nef* fusion protein, classified in class 435, subclass 7.1.

f. Group VI, claims 83-84, drawn to a **compound** capable of inhibiting nef gene activity, classified in class 424, subclass 278.1.

g. Group VII, claim 86, drawn to a **therapeutic composition** comprising a non-pathogenic HIV-1 isolate that is also capable of expressing a **ribozyme or antisense molecule**, classified in class 536, subclass 24.5.

h. Group VIII, claims 87-93, drawn to a **non-pathogenic viral isolate** comprising a modified genome capable of expressing an **antisense or ribozymal molecule** that inhibits HIV-1 replication, classified in class 424, subclass 93.2.

i. Group IX, claims 94-110 and 115, drawn to a **method for determining the pathogenicity** of an HIV-1 strain through the detection of **deletion mutations** in the viral genome, classified in class 435, subclass 91.2.

j. Group X, claims 111-114 and 116, drawn to a **method for determining the pathogenicity** of an HIV-1 strain by employing a **peptide-based assay**, classified in class 435, subclass 34.

k. Group XI, claims 117, drawn to a **peptide** comprising SEQ ID NO.: 801 or a fragment thereof, classified in class 530, subclass 326.

l. Group XII, claims 118, drawn to **antibodies** that bind to a peptide comprising SEQ ID NO.: 801 or a fragment thereof, classified in class 530, subclass 387.1.

m. Group XIII, claim(s) , drawn to a **method of risk assessment** employing a peptide defined by SEQ ID NO.: 801, classified in class 436, subclass 506.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I, VI-VIII, XI, and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case each of the aforecited inventions is directed toward a different product (e.g., non-pathogenic HIV-1 isolate, antiviral compound, therapeutic composition, modified non-pathogenic HIV-1 isolate expressing an antisense molecule, peptide, and antibody) with

different structures and functions. Accordingly, each invention is clearly drawn toward a different inventive concept.

5. Inventions II-V, IX, X, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case each of the aforecited inventions is directed toward a different methodology that employs different scientific reagents and methodology steps, and is directed toward a different scientific objective (e.g., methods of inhibiting viral infection, methods of vaccinating subjects, antiviral screening methods, methods for assessing viral pathogenicity, and methods of risk assessment). Accordingly, each invention is clearly drawn toward a different inventive entity.

6. Inventions I/VI-VIII/XI/XII and II-V/IX/X/XIII are unrelated except where noted in subsequent paragraphs seven through nine. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, none of the products are required to practice the methodologies and the methodologies do not require any of the identified products in order to be performed. Therefore, each invention is clearly drawn toward a different inventive concept.

7. Inventions I and II/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

¶ 806.05(h)). In the instant case, the non-pathogenic HIV-1 isolate can be employed in a number of different methodologies such as antiviral screening assays, the generation of immunological reagents, and as a diagnostic reagent in diagnostic assays. Moreover, the cited methodologies can employ materially different products such as subunit vaccines or known antivirals.

8. Inventions XI and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. ¶ 806.05(h)). In the instant case the peptide of Group XI can be employed in materially different processes such as the generation of immunological reagents or affinity purification protocols. Moreover, the method can employ materially different products such as PCR primers for the detection of non-pathogenic HIV-1 isolates.

9. Inventions I and IV are related as product made and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different products, or (2) the product as claimed can be made by another and materially different process (M.P.E.P. ¶ 806.05(f)). In the instant case the non-pathogenic isolate can be made through a materially different process such as PCR amplification. Moreover, the process claimed can be employed to make materially different products such as pathogenic HIV-1 isolates.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, requirement for independent

searches, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim Cancellation

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Correspondence

12. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1641.**

13. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

14. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122,

respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 160(receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1641

22 February, 2000

LAURIE SCHEINER
PRIMARY EXAMINER

RESTRICTION/ELECTION FACSIMILE TRANSMISSION

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IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.